

- b.) administering at least one dose of an effective amount of a first therapeutic growth factor protein formulation by inhalation therapy;
- c.) monitoring one or more clinical indicators of acute coronary artery disease;
- d.) determining, based upon monitoring the one or more clinical indicators of coronary artery disease, whether an additional dose of a therapeutic growth factor protein formulation is necessary;
- e.) depending on the results of the step d.), administering one or more additional doses of a second growth factor protein formulation; and
- f.) repeating steps c.) through e.) until there is a clinical indication of amelioration of the symptoms of acute coronary artery disease in the patient, or until there is a contraindication to continued treatment.

17. (New) The method of claim 16. (New), wherein the second growth factor protein formulation is administered by a method of delivery more invasive than the method of delivery utilized for administration of the first growth factor protein formulation.

18. (New) The method of claim 16. (New), wherein the second growth factor protein formulation is administered by the same method of delivery utilized for administration of the previous dose.

19. (New) The method of claim 16. (New), wherein the one or more clinical indicators of acute coronary artery disease are selected from the group consisting of levels of CPK-MB, electrocardiogram tracings, and chest pain.

20. (New) The method of claim 16. (New), wherein the protein formulation comprises a growth factor protein selected from the group consisting of FGF-1, FGF-2, VEGF, and mixtures thereof.

21. (New) The method of claim 16. (New), wherein the symptoms of acute coronary artery disease are brought on by a condition selected from the group consisting of myocardial infarct, unstable angina, and acute anginal attack.

22. (New) The method of claim 16. (New), wherein the method of delivery of the second growth factor protein formulation is selected from the group consisting of oral inhalation, intravenous administration, intracoronary infusion, intrapericardial injection, myocardial introduction via catheter during cardiac catheterization, and direct myocardial injection.

23. (New) The method of claim 16. (New), wherein the growth factor formulation administered in step e.) and subsequent steps is the same as the growth factor formulation administered initially.

24. (New) The method of claim 16. (New), wherein the growth factor formulation administered in step e.) and subsequent steps is different from the growth factor formulation administered initially.

25. (New) A method for the administration of therapeutic amounts of a growth factor protein formulation in the treatment of coronary artery disease comprising the step of delivering the protein formulation by inhalation therapy.

26. (New) The method of claim 25. (New), wherein the protein formulation is a dry powder formulation.

27. (New) The method of claim 25. (New), wherein the protein formulation is a liquid aerosol formulation.

28. (New) A method for monitoring the clinical effectiveness of administration of a potentially therapeutic pharmaceutical formulation in the treatment of acute coronary artery disease, the method comprising the steps of:

- a.) obtaining a sample of a biological fluid from a patient displaying symptoms of acute coronary artery disease;
- b.) performing an assay of the biological fluid to determine an amount of CPK-MB present in the fluid;
- c.) administering a therapeutic amount of a pharmaceutical formulation to the patient; and

d.) repeating steps b.) and c.) until the assayed level of CPK-MB in the biological fluid indicates the clinical effectiveness of the administration of the pharmaceutical formulation.

29. (New) The method of claim 42. (New), wherein the pharmaceutical formulation comprises a growth factor protein.

30. (New) The method of claim 42. (New), wherein the pharmaceutical formulation comprises a growth factor protein selected from the group consisting of FGF-1, FGF-2, VEGF, and mixtures thereof.

31. (New) The method of claim 42. (New), wherein the acute symptoms of heart disease are brought on by a condition selected from the group consisting of myocardial infarct, unstable angina, an acute anginal attack, and reperfusion injury.

32. (New) The method of claim 31. (New), wherein the reperfusion injury is induced by a procedure selected from the group consisting of thrombolytic therapy, bypass surgery and angioplasty.

33. (New) A method for monitoring the clinical effectiveness of administration of a potentially therapeutic pharmaceutical formulation in the treatment of acute coronary artery disease, the method comprising the steps of:

- a.) selecting a patient displaying symptoms of acute coronary artery disease;
- b.) monitoring one or more clinical indicators of acute coronary artery disease;
- c.) administering a therapeutic amount of a pharmaceutical formulation to the patient; and
- d.) repeating steps b.) and c.) until the one or more indicators of acute coronary artery disease reflect the clinical effectiveness of the administration of the pharmaceutical formulation, or until there is a contraindication to continued treatment.

34. (New) The method of claim 33. (New), wherein the one or more clinical indicators of acute coronary artery disease are selected from the group consisting of levels of CPK-MB, electrocardiogram tracings, and chest pain.

35. (New) A method for the systematic, multi-tiered treatment of chronic coronary artery disease by delivery of a formulation comprising one or more therapeutic growth factor proteins, the method comprising the steps of:

- a.) selecting a patient displaying symptoms of chronic coronary artery disease;
- b.) administering at least one dose of an effective amount of a first therapeutic growth factor protein formulation by inhalation therapy;
- c.) monitoring one or more clinical indicators of chronic coronary artery disease;
- d.) determining, based upon monitoring the one or more clinical indicators of chronic coronary artery disease, whether an additional dose of a therapeutic growth factor protein formulation is necessary;
- e.) depending on the results of the step d.), administering one or more additional doses of a second growth factor protein formulation; and
- f.) repeating steps c.) through e.) until there is a clinical indication of amelioration of the symptoms of chronic coronary artery disease in the patient, or until there is a contraindication to continued treatment.

36. (New) The method of claim 35. (New), wherein the amelioration of symptoms is achieved as the result of a clinically significant amount of angiogenesis.

37. (New) The method of claim 35. (New), wherein the second growth factor protein formulation is administered by the same method of delivery utilized for administration of the previous dose.

38. (New) The method of claim 35. (New), wherein the second growth factor protein formulation is administered by a method of delivery more invasive than the method of delivery utilized for administration of the first growth factor protein formulation.

39. (New) The method of claim 35. (New), wherein the one or more clinical indicators of chronic coronary artery disease are selected from the group consisting

of frequency and intensity of anginal symptoms, myocardial perfusion, electrocardiogram tracings, scores on quantitative angina scales, and angiography.

40. (New) The method of claim 35. (New), wherein the protein formulation comprises a growth factor protein selected from the group consisting of FGF-1, FGF-2, VEGF, and mixtures thereof.

41. (New) The method of claim 35. (New), wherein the method of delivery of the growth factor protein formulation is selected from the group consisting of oral inhalation, intravenous administration, intracoronary infusion, intrapericardial injection, myocardial introduction *via* catheter during cardiac catheterization, introduction during transmyocardial laser revascularization, and direct myocardial injection.

42. (New) The method of claim 35. (New), wherein the growth factor formulation administered in step e.) and subsequent steps is the same as the growth factor formulation administered initially.

43. (New) The method of claim 35. (New), wherein the growth factor formulation administered in step e.) and subsequent steps is different from the growth factor formulation administered initially.

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44. (New) A method for the systematic, multi-tiered treatment of coronary artery disease by delivery of a formulation comprising one or more therapeutic growth factor proteins, the method comprising the steps of:

- a.) selecting a patient displaying symptoms of acute coronary artery disease;
- b.) administering at least one dose of an effective amount of a first therapeutic growth factor protein formulation by a method of delivery that is the least invasive available, and consistent with the clinical condition of the patient;
- c.) monitoring one or more clinical indicators of acute coronary artery disease;
- d.) determining, based upon monitoring the one or more clinical indicators of coronary artery disease, whether an additional dose of a therapeutic growth factor protein formulation is necessary;

- e.) depending on the results of the step d.), administering one or more additional doses of a second growth factor protein formulation; and
- f.) repeating steps c.) through e.) until there is a clinical indication of amelioration of the symptoms of acute coronary artery disease in the patient, or until there is a contraindication to continued treatment.

45. (New) The method of claim 44. (New), wherein the second growth factor protein formulation is administered by a method of delivery more invasive than the method of delivery utilized for administration of the first growth factor protein formulation.

46. (New) The method of claim 44. (New), wherein the second growth factor protein formulation is administered by the same method of delivery utilized for administration of the previous dose.

47. (New) The method of claim 44. (New), wherein the initial method of delivery of the first therapeutic growth factor comprises inhalation therapy.

48. (New) The method of claim 44. (New), wherein the one or more clinical indicators of acute coronary artery disease are selected from the group consisting of levels of CPK-MB, electrocardiogram tracings, and chest pain.

49. (New) The method of claim 44. (New), wherein the protein formulation comprises a growth factor protein selected from the group consisting of FGF-1, FGF-2, VEGF, and mixtures thereof.

50. (New) The method of claim 44. (New), wherein the symptoms of acute coronary artery disease are brought on by a condition selected from the group consisting of myocardial infarct, unstable angina, and acute anginal attack.

51. (New) The method of claim 44. (New), wherein the method of delivery of the second growth factor protein formulation is selected from the group consisting of oral inhalation, intravenous administration, intracoronary infusion, intrapericardial injection, myocardial introduction via catheter during cardiac catheterization, and direct myocardial injection.